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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,720	07/17/2000	Martin Nicklin	MSA-021.01	7893

25181 7590 03/12/2002

FOLEY, HOAG & ELIOT, LLP
PATENT GROUP
ONE POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	13

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/617,720	Nicklin et al
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 1, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above, claim(s) *1-11, 13, 22, and 23* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *12, 14-21, and 24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7, 6

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II (claims 12, 14-21 and 24, and SEQ ID NO:1) in Paper No:12 filed on 01 February 2002 is acknowledged. The traversal is on the grounds that the Examiner has not set forth a convincing argument that searching and examining the inventions of Groups I and II would be unduly burdensome and that Applicants belief that the examination of the two groups could be conducted in a single prior art search. Applicants further traverse the restriction of the SEQ ID Nos:1-4. Applicants request that elected SEQ ID NO:1 should be searched in conjunction with each of two alternative 5' ends, namely SEQ ID Nos: 2 and 3.

Applicant's first ground of traversal is not found persuasive, because the inventions of Groups I and II are classified in different classes and sub-classes and each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. (MPEP § 808.02). Applicant's second ground of traversal is found persuasive, therefore, SEQ ID Nos:2 and 3 will be searched in conjunction with SEQ ID NO:1.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-11, 13 and 22-23 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Specification

2a. The disclosure is objected to, because the specification asserts repeatedly, that a nucleic acid molecule comprising the cDNA encoding the full length hIL-IL1 protein was deposited at ATCC, on XXXX, XX, 199 and has been assigned ATCC Designation No.XXXXXX. However, the specification must provide the actual Accession Number for said deposit and the date in which said deposit was actually made, instead of the XXXXXXs. Appropriate correction is required.

Claim objections:

2b. Claims 12, 14, 18 and 19 are objected to because of the following informalities: claims 12, 14, 18 and 19 recite non-elected SEQ ID No:4. Appropriate correction is required.

2c. Claims 18 and 19 are objected to, because these claims recite Accession Numbers for EST sequences. However, it is suggested that said sequences be identified using a sequence identifier instead of Accession Numbers.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 17 and 19 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 17 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art

to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that the gene insert of the vector recited in claims 17 and 19 is required to practice the claimed method. As such the vector must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If the gene insert of vector is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the vector.

The specification on page 4, fist paragraph, states that a cDNA encoding the full length hIL-IL1 was deposited at the American Type Tissue Culture Collection, however, the specification neither provides the date that this deposit was made nor an ATCC number. If a deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that (a) during pendency of the application, access to the invention will be afforded to the Commissioner upon request, (b) all restrictions upon availability to the public will be irrevocable removed upon granting of the patent, © the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the

patent, whichever is longer, (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807) and (e) the deposit will be replaced if it should ever become inviable.

3b. Claims 12, 14-17, 20, 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:1, does not reasonably provide enablement for an isolated nucleic acid comprising a nucleotide sequence which is at least 70%-90% identical to the nucleotide sequence of SEQ ID NO:1 or a complement thereof or which hybridizes thereto. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

Claim 12 is drawn to an isolated nucleic acid which comprises at least 70% of SEQ ID NO:1, however, the specification does not disclose a nucleic acid sequence having at least 70% identity to SEQ ID NO:1, claim 20 is drawn to an isolated nucleic acid which is at least 75% to SEQ ID NO:2 and claim 21 is drawn to an isolated nucleic acid that is at least 95% of SEQ ID NO:3. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polynucleotide having at least 70%, 75% or 95% sequence identity to SEQ ID Nos:1, 2 or 3 respectively, that would retain the desired function of the native sequence, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polynucleotide or a polypeptide encoded thereby, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number

of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990), and In re Wands, 8USPQ2d, 1400 (CAFC 1988). In In re Wands, page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a polynucleotide whose nucleotide sequence deviates from that of as SEQ ID NO:1 by as much as 30% that would encode the human IL-IL-1 protein of the instant invention. The nucleic acid of SEQ ID NO:1 comprises 2563, including which includes untranslated regions and a 465 open reading frame which encodes a protein that comprises 155 amino acid residues. Applicants do not teach a nucleic acid that shares 70% identity to SEQ ID NO:1 and encodes the desired protein. Instant specification describes SEQ ID No:2 and 3 as being two alternate 5' ends of human IL-IL1 gene, (see page 4). SEQ ID NO:2 comprises 39 and SEQ ID NO:3 comprises 2-42 nucleotides, and instant specification does not teach which 25% and which 5% of SEQ ID Nos:2 and 3, respectively could be altered while still identifying the two SEQ ID NOs as 5' alternate ends of the of the human IL-IL1. To practice the instant invention in a manner consistent

with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

4c. Claims 12, 14-17, 20, 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only discloses the nucleic acid of nucleotide sequence set forth in SEQ ID NO:1, 2 and 3, and therefore the written description is not commensurate in scope with claims 1, 20 and 21 which is drawn a nucleic acid comprising a sequence having at least 70%, 75% and 95% to SEQ ID Nos:1, 2 and 3 respectively.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of SEQ ID NO: NOs:1, 2 and 3 the skilled artisan cannot envision the detailed structure of the encompassed polypeptide or the polynucleotide encoding such and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Therefore, it does not appear that the inventors were in possession of a a nucleic acid comprising at least 70% of SEQ ID NO:1, 75% of SEQ ID NO:2 or 95% of SEQ ID NO:3.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5a. Claims 14 and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5b. Claims 14 and 19 are rejected as vague and indefinite because the claim sub-part [c] recites "An isolated nucleic acid sequence which hybridizes under stringent conditions to .....", stringent conditions is a conditional term and renders the claims indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be "stringent."

5c. Claims 17 and 19 are vague and indefinite for reciting "..... XXXXXX or XXXXXX....". applicants must recite an actual Accession Number for the claimed vector. Appropriate correction is required.

Claim rejections-35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6a. Claims 12, 14-16, 18-19, 20-21 and 24 are rejected under 35 U.S.C *§ 102*(b) as being anticipated by Ford et al (U.S Patent 6,294,655).

Ford et al teach isolated polynucleotides encoding Interleukin-1 Receptor Antagonists, said nucleic acids which comprise a label, expression vectors containing said polynucleotides, host cells comprising said vectors, method of making the encoded polypeptides and methods of using said polypeptides, (see abstract and column 3, line 3 through column 5, line 3 and column 9, 1-4). One of the polynucleotide disclosed by Ford et al shares 97.1% sequence similarity to the instantly claimed polynucleotides of SEQ ID NO:1, and another shares 86.6%, from nucleotide 1-2563, shares 100% to instant SEQ ID NO:3 and shares 94.9% to instant SEQ ID NO:2, (See attached copies of the comparisons of SEQ ID NO:1 claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISONS 'A-D').

Instant claims 12, 14-16, 18-21 and 24 are drawn to an isolated human nucleic acid comprising a nucleotide sequence which is at least 70% identical to the entire sequence set forth in SEQ ID NO:1, or to an isolated nucleic acid which hybridizes to nucleotide 310-2562 of SEQ ID NO:1, or which hybridizes to nucleotide 1-29 of SEQ ID NO:2 or SEQ ID NO:3, or an isolated nucleic acid which is at least 75% identical to SEQ ID NO:2 or 90% identical to SEQ ID NO:3, and one of these nucleic acids which further comprises a label. The polynucleotides disclosed by Ford et al meet all

of the limitations recited in instant claims 12, 14-16, 18-19, 20-21 and 24, since the polynucleotides disclosed by Ford et al share 70%, 75% and 90% to SEQ ID Nos:1-3, respectively, and since they would be expected to hybridize to nucleotide 310-2562 of SEQ ID NO:1, and nucleotide 1-29 of SEQ ID NO:3. Therefore, Ford's et al reference anticipates the instant claims 12, 14-16, 18-21 and 24 in the absence of any evidence to the contrary.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wedensday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
26 February 2002

Yvonne Eyler

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600